m2207n HFI-35 (Purged)

DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

Food and Drug Administration
Baltimore District Office
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3461 x122
FAX: (410) 962-2219

November 23, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Mary S. Riepe, President
The Warner-Graham Company
160 Church Lane
P. O. Box 249
Cockeysville, Maryland 21030

Dear Ms. Riepe:

A Food and Drug Administration (FDA) inspection was conducted from October 23 through November 2, 1998 at your Cockeysville, Maryland facility. The inspection confirmed that you repackage Alcohol, USP and Dehydrated Alcohol, USP. These are drugs as defined by Section 201(g)(1)(A) of the Federal Food, Drug, and Cosmetic Act (the Act), in that they are recognized in the official United States Pharmacopeia (USP). The strength, quality, and purity of a USP drug must conform to standards set forth in the USP as determined by USP tests or methods of assay.

During our inspection, deviations from the Current Good Manufacturing Practice (CGMP) requirements (Title 21, Code of Federal Regulations (CFR), Part 211) were observed. These deviations cause your products to be adulterated within the meaning of Section 501(a)(2)(B) of the Act, in that the methods used in, or the facilities or controls used for, manufacturing, processing, packing, storage, or holding, are not in conformance with CGMP regulations.

The deviations included the following:

- Failure to assure conformity of incoming alcohol with all appropriate specifications for purity, strength, and quality, in that you failed to test for conformity with all appropriate written specifications or, in addition to receiving a report of analysis from your supplier, failed to perform a specific identification test and to establish the reliability of your suppliers' analyses through appropriate validation of the said test results at appropriate intervals.

- Finished drug product Alcohol, USP, fails to conform to appropriate specifications. For example, the "Assay by GC" for lot 008812 is 91.7% which is outside the USP specification of not less than 92.3% and not more than 93.8% by weight, or not less than 94.9% and not more than 96.0% by volume at 15.56°C (60°F).

- Failure to establish the accuracy, sensitivity, specificity, and reproducibility of test methods.

- Failure to establish scientifically sound and appropriate specification, standards, and test procedures designed to assure that the components and drug products conform to appropriate standards of identity, strength, quality, and purity. For example, your gas chromatographic method for determining percent alcohol is inadequate. First, the thermal conductivity detector in your instrument responds differently to water and alcohol, which means their responses cannot be directly compared. Therefore, it is incorrect to assume that the percent printed out on the chromatogram under "CONC" is the actual percent alcohol. Second, an alcohol reference standard is not used to determine the actual alcohol concentration. Third, the method fails to conform to the USP 23 method <611> Alcohol Determination Method II--Gas-Liquid Chromatographic Method.

- Failure to calibrate or document the calibration of instruments, apparatus, gauges, and recording devices at suitable intervals.

- Failure to assure that each person engaged in the manufacturing, processing, packing, or holding of the drug product has the education and training to enable him or her to perform their assigned functions.

- Failure to establish a quality control unit with the responsibility and authority to approve or reject all components, containers, closures, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated.

- Failure to have a second person independently check or review records for accuracy, completeness, and compliance with established standards, and to sign the records.

At the conclusion of the inspection, you were given a written list of inspectional observations (FDA-483) which was discussed with you.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to all requirements of the Act and regulations. The specific violations noted in this letter and in the FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If you determine the causes to be systems problems, you must promptly initiate permanent corrective action.

Federal agencies are advised of the issuance of all Warning Letters concerning drug products so that they may take this information into account when considering the award of contracts. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Baltimore District, 900 Madison Avenue, Baltimore, Maryland 21201, to the attention of Thomas C. Knott, Compliance Officer. Mr. Knott can be reached at (410) 962-3461, extension 122.

Sincerely,

William M. Ment

William M. Ment
Acting Director, Baltimore District